DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

722

FOOD & DRUG ADMINISTRATION
466 FERNANDEZ JUNCOS AVENUE
SAN JUAN, P.R. 00901-3223

October 15, 1997

WARNING LETTER
SJN-98-01

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

José Algarín
President & CEO
Sky Caterers Inc.
P.O. Box 38097 Airport Sta.,
San Juan. PR 00937

Dear Mr. Algarín:

The United States Food & Drug Administration (FDA) inspected your catering service operation, Carolina Catering Corporation, DBA Sky Catering, located at Luís Muñoz Marín International Airport, Carolina, PR, on September 24 & 26, 1997.

Our investigators found deficiencies which are considered violations of Title 21 Code of Federal Regulations, Part 1250 (21 CFR 1250) and Section 361 of the Public Health Service Act.

During the inspection, the following violations were noted:

1. Inadequate control of insects in the following areas:

   Six live flies on the food and non-food contact surfaces of the kitchenware located in the dish washing area.

   Two live flies on the surface of a paper bag of wheat flour located in the dry goods storage area of the bakery.

   A live cockroach on the floor under the multi-tank conveyor machine used to clean and sanitize soiled equipment from the aircraft.

2. The process used to sanitize large kitchenware and utensils failed to meet the temperature and chemical sanitizing agent concentration requirements because the temperature of the chemical sanitizing rinse at the multi-tank conveyor machine

was at 174° F instead of the required 180° F. There was also no chemical sanitizing rinse in the third compartment of the three compartment sink used for manual cleaning and sanitizing of large pans, pots and other kitchenware.

3. The food contact surfaces of plastic and ceramic dishes, the Hobart mixer and food transport trolleys were observed to have food residues remaining after washing.

In view of the critical nature of these violations, and pursuant to the Food & Drug Administration's authority under section 361 of the Public Health Service Act, we are classifying your facility as "PROVISIONAL" for interstate carrier use for a period of thirty (30) days. A "PROVISIONAL" classification means that the facility may continue to operate; however, significant correction of violations must be made by the expiration date. On or about that date, a re-inspection of this facility will be conducted to assure that corrections meet FDA requirements. If significant corrections are not made at the time of the next inspection, the facility will be classified as "NON-APPROVED" for carrier use. This actions is being taken after a score of 78 on form FDA-2420.

The observations contained in this letter are not intended to be an all-inclusive list of violations at your facility. It is your responsibility to assure that all requirements of 21 CFR 1250 and Section 361 of the Public Health Service Act are being met. Failure to comply with these regulations may result in regulatory action without further notice.

Please advise this office within fifteen (15) days of the receipt of this letter regarding the measures you have implemented to correct the violations. Your response should include a discussion of any delays you foresee in achieving correction and a deadline by which correction can be expected.

Your response should be directed to Mary L. Mason, Compliance Officer at the address listed above. Should you require any assistance in understanding the contents of this letter or if you desire a meeting with the agency staff Ms. Mason can be reached by telephone at (787) 729-6894.

Sincerely,

Samuel Jones
District Director

Enclosures:

Copy of form FDA-483
Copy of Form FDA-2420 (9/26/96)
Copy of 21 CFR 1250